

Claims 15-23 and 25-31 are again rejected under 35 USC 103 over Asche, USP 4,917,886. Applicant traverses the rejection.

The Examiner has significantly mis-stated the teaching of Asche and has drawn erroneous conclusions based on this error. The Examiner states that Asche teaches 0.1-10% by weight of an NSAID *such as diclofenac sodium*. Stated this way, it appears that Asche teaches 0.1% diclofenac sodium. This would support the argument that a broad range of compositions is obvious. However, there is no such teaching in this reference.

The Examiner refers to col 7, lines 45-54 in support of the rejection. However, the teaching there is that for the preferred actives, (e.g. diclofenac), the range is 1-5%, i.e. at least one order of magnitude greater than 0.1%. Although Asche does teach a range of 0.1-10%, this range applies only to the broad genus of NSAIDs. At col 7 and continuing to col 8, line 34 Asche teaches 22 active NSAID compounds and a very large number of possible salt forms thereof. This combination of actives and salts amounts to well over 1000 compounds. This is not the basis for the statement that Asche teaches 0.1% diclofenac sodium, especially since the only references in Asche to this specific compound and an amount thereof is 1.% diclofenac (at the bottom of col. 2) and even greater amounts in Examples 1-4. Furthermore, the examples of Asche utilize the diethylammonium or triethanolammonium salt forms of diclofenac, and all rely on an organic amine to adjust pH. None of this suggests ammonia, sodium hydroxide and potassium hydroxide to adjust the pH, as in the present claims. Thus, a fair reading of Asche does not suggest a topical emulsion gel composition as presently claimed wherein the active is a specific salt of diclofenac in a low dose concentration which uses ammonia, sodium hydroxide, or potassium hydroxide to adjust the pH.


The Examiner's refusal to interpret certain claims narrowly ("consisting essentially of" is to be read as "comprising") absent an indication in the claims or specification what the basic and novel characteristics are is not understood. The Examiner's attention is directed to page 2, paragraphs 1 and 2 of the specification.

It is requested that the amendment be entered, since it is deemed to place at least certain claims in condition for allowance and to otherwise reduce the issues on appeal. The Examiner is requested to reconsider all bases for rejection, objection, and claim interpretation and to pass the case to issue.

It is requested that the period for response to the Action dated August 19, 2008 be extended two months to January 19, 2009. Applicant requests that any additional claim fees, or other fees necessitated by this paper, be charged to Deposit Account No. **50-4395** in the name of Novartis Consumer Health, Inc.

Respectfully submitted,

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